



Robert Greene Sterne  
Edward J. Kessler  
Jorge A. Goldstein  
David K.S. Conrad  
Robert W. Esmond  
Tracy-Gene G. Durkin  
Michael A. Cimbal  
Michael B. Ray  
Robert E. Sokol  
Eric K. Steffe  
Michael Q. Lee  
Steven R. Ludwig  
John M. Covert  
Linda E. Alcorn  
Robert C. McGonig  
Donald J. Featherstone  
Lawrence B. Bergshteyn  
Michael V. Messinger

Judith U. Katz  
Timothy J. Sheehy, Jr.  
Patrick E. Garrett  
Heidi L. Kays  
Edward W. Yee  
Albert L. Ferro  
Donald R. Banowitz  
Peter A. Jackman  
Teresa U. Medler  
Jeffrey S. Weaver  
Kenneth P. Patterson  
Vincent L. Capuano  
Eldora Ellison Floyd  
Thomas C. Fiale  
Brian J. Del Buono  
Virgil Lee Beaton  
Kimberly H. Reddick  
Theodore A. Wood

Elizabeth J. Haanes  
Joseph S. Ostroff  
Frank R. Coningham  
Christine M. Uhlir  
Rae Lynn Prensaman  
Jane Shenshenovich  
George S. Bardmesser  
Daniel A. Klein  
Jason D. Eisenberg  
Michael D. Specht  
Andrea J. Kamage  
Tracy L. Muller  
LuAnne M. DeSantis  
John J. Figueroa  
Aino E. Summerfield  
Tara S. Coston  
Aric W. Ledford  
Jessica L. Parizo

Timothy A. Doyle  
Gaby L. Longworth  
Nicole D. Dwyer  
Ted A. Eberle  
Hyud C. Iyer  
Registered Patent Agents  
Karen R. Markowicz  
Nancy J. Lesh  
Helene C. Carlson  
Matthew J. Dowd  
Aaron L. Schwartz  
Karlina Y. Pel Quach  
Bryan L. Stachon  
Robert A. Schwartzman  
Yeresa A. Colella  
Jeffrey S. Lundgren  
Victoria S. Rutherford

Eric D. Hayes  
Michelle K. Holubek  
Robert H. DeSantis  
Simon J. Elbert  
Julia A. Heider  
Mira Mukherjee  
Scott M. Woodhouse

Of Counsel  
Kenneth C. Bass III  
Evan R. Smith  
Marvin C. Gutzke

\*Admitted only in Maryland  
\*Admitted only in Virginia  
\*Practice Limited to  
Federal Agencies

May 19, 2004

WRITER'S DIRECT NUMBER:  
(202) 772-8560

INTERNET ADDRESS:  
RESMOND@SKGF.COM

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Art Unit 1644

Mail Stop AF

Re: U.S. Utility Patent Application  
Application No. 09/920,332; Filed: August 2, 2001  
For: Method of Identifying Immunosuppressive Agents  
Inventors: Kasibhatla *et al.*  
Our Ref: 1735.0470001/RWE/ALS

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply Under 37 C.F.R. § 1.116; and
2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

RWE/dab  
265916\_1.DOC  
Enclosure



Post. and Mail  
**BUX AF**

AF/11644

Reply Under 37 C.F.R. § 1.116  
Expedited Procedure - Art Unit 1644

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kasibhatla *et al.*

Appl. No.: 09/920,332

Filed: August 2, 2001

For: **Method of Identifying  
Immunosuppressive Agents**

Confirmation No.: 5774

Art Unit: 1644

Examiner: Huynh, Phuong N.

Atty. Docket: 1735.0470001/RWE/ALS

**Reply Under 37 C.F.R. § 1.116**

**Mail Stop AF**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated February 26, 2004 (hereinafter "Office Action"), Applicants submit the following Remarks. Claims 1, 2, 4-7, 9-13, 28-31 and 36-44 are pending in the application, with claims 1, 28 and 31 being the independent claims. Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Rejections under 35 U.S.C. § 103***

Claims 1-2, 4-7, 9-11, 28-31 and 36-42 are rejected under 35 U.S.C. §103(a) as being unpatentable over Evans, D. L. *et al.*, *Cancer Research*, 54: 1596-1603 (1994) ("Evans *et al.*") in view of Porter, D. H. *et al.*, *Analytical Biochemistry*, 123: 41-48 (1982) ("Porter *et al.*") and U.S. Patent No. 6,342,611 ("the '611 patent"). Office Action, pages 2-8. Claims 12-13, 43 and 44 are also rejected under 35 U.S.C. §103(a) as being

unpatentable over Evans *et al.* in view of Porter *et al.* and the '611 patent as applied to claims 1-2, 4-7, 9-11, 28-31 and 36-42 and further in view of Wesselborg, S. *et al.*, *Eur. J. Immunol.*, 23: 2707-2710 (1993) ("Wesselborg *et al.*"). Office Action, pages 9-13.

Applicants respectfully traverse the rejection.

Applicants respectfully assert that the '611 patent cannot properly be used in a rejection under 35 U.S.C. § 103(a) because of the provision found in 35 U.S.C. §103(c).

This section provides as follows:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 U.S.C. § 103(c). Moreover, the MPEP explicitly states that this section "applies to all utility, design and plant patent applications filed on or after November 29, 1999, . . . ."

MPEP (Eighth, rev. 1) § 706.02(k), page 700-45 (February 2003). Applicants' application was filed on August 2, 2001, and the above section is applicable.

The subject matter of the captioned application was developed by Shailaja Kasibhatla, Douglas R. Green and Ben Tseng. See original executed declaration filed on November 15, 2001. In contrast, the subject matter of the '611 patent was developed by Eckard Weber, Sui Xiong Cai, John F.W. Keana, John A. Drewe and Han-Zhong Zhang. See first page of the '611 patent. Hence, the subject matter of the '611 patent was developed by another person.

The '611 patent qualifies as prior art (if it qualifies as prior art at all) only under one or more of subsections (e), (f), and (g) of 35 U.S.C. § 102. 35 U.S.C. § 102(a) and (b) are not applicable because the '611 patent published on January 29, 2002, which is

after the filing date of the instant application (August 2, 2001) and after the priority date of the instant application (August 3, 2000). Furthermore, 35 U.S.C. § 102(c) and (d) are not relevant or applicable to the '611 patent. Hence, the '611 patent qualifies as prior art (if it qualifies as prior art at all) only under one or more of subsections (e), (f), and (g) of 35 U.S.C. § 102.

Finally, the subject matter of the '611 patent and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. The MPEP sets forth the requisite evidence required to establish common ownership:

The following statement is sufficient evidence to establish common ownership of, or an obligation for assignment to, the same person(s) or organizations(s):

Applications and references (whether patents, patent applications, patent application publications, etc.) will be considered by the examiner to be owned by, or subject to an obligation of assignment to the same person, at the time the invention was made, if the applicant(s) or an attorney or agent of record makes a statement to the effect that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person.

MPEP (Eighth, rev. 1) § 706.02(I)(2)(II), p. 700-53 (February 2003) (*referring to* "Guidelines Setting Forth a Modified Policy Concerning the Evidence of Common Ownership, or an Obligation of Assignment to the Same Person, as Required by 35 U.S.C. 103(c)," 1241 O.G. 96 (December 26, 2000)). The undersigned hereby asserts that the ownership of the present application and the '611 patent were, at the time the present invention was made, owned by, or subject to an obligation of assignment to the same person. Hence, Applicants have provided sufficient evidence establishing that the subject matter of the '611 patent and the claimed invention were, at the time the

invention was made, owned by the same person or subject to an obligation of assignment to the same person. Accordingly, Applicants have demonstrated that because the '611 patent falls within the ambit of 35 U.S.C. § 103(c), it cannot properly be used in a rejection under 35 U.S.C. §103(a).

Furthermore, the Examiner bears the initial burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. In particular, the MPEP sets forth the criteria necessary to satisfy this burden:

To establish a *prima facie* case of obviousness, three basic criteria *must* be met. First, there *must* be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there *must* be a reasonable expectation of success. Finally, the prior art reference (or references when combined) *must* teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success *must* both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

MPEP (Eighth, rev. 1) § 2142, page 2100-124 (February 2003), emphasis added. Applicants respectfully assert that the references cited in support of the 35 U.S.C. § 103 rejection do not meet these criteria, and that consequently the Examiner has not established a *prima facie* case of obviousness.

Hence, the new grounds of rejection under §103 have been overcome and Applicants respectfully ask the Examiner to reconsider and withdraw the rejection under 35 U.S.C. §103(a).

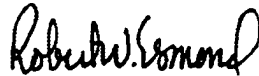
***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond  
Attorney for Applicants  
Registration No. 32,893

Date: May 19, 2004

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600